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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,025	03/02/2004	Robert Frederick Veasey	10-296	9747

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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08/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,025

Applicant(s)

VEASEY ET AL.

Examiner

SHEFALI D. PATEL

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10 and 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-4,7-9,11-15,17 and 18 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgments

1. In the reply, filed on June 3, 2010, Applicant amended claims 1 and 2.
2. Applicant cancelled claim 22.
3. In the non-final rejection of January 6, 2010, Examiner rejected claims 1 and 22 under 35 USC 112, 2nd paragraph, as it was unclear which structures in the specification correspond to the means-plus-function terms used in the claims. Applicant amended claim 1 to remove the means-plus-function terms and cancelled claim 22. Rejection is withdrawn.
4. Currently, claims 1-4, 7-9, 11-15, 17, and 18 are under examination.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Burroughs et al (US 6,221,046).

In regards to claim 1, Burroughs et al teaches a pen-type injector (Figures 1-15) comprising:

- a. a housing (housing [22])

- b. a cartridge (cartridge [40]) containing medicinal product, the cartridge being retained within the housing
- c. a dose dial sleeve (dial mechanism [34]) for selecting a dose of medicinal product to be expelled
- d. a piston rod (leadscrew [38]) for expelling the selected dose of medicinal product, wherein the housing comprises a unitary housing within which the dose dial sleeve and the piston rod are moveably retained and wherein the cartridge is enclosed within the housing together with the dose dial sleeve and the piston rod (Figure 1)
- e. a cylindrical insert (ledges [178][180]) rotationally and axially fixed to the housing [22] and threadedly engaged to the piston rod [38] (column 10, lines 26-28), where the insert has a cylindrical portion extending longitudinally in a proximal direction enclosing a portion of the piston rod (Figure 1)

Response to Amendment

7. The reply filed on June 3, 2010, is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): the text of withdrawn claims 5, 6, 10, and 16 has been omitted and should be presented. Text should only be omitted for cancelled claims: *The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims*

of the status of "withdrawn" or "previously presented". MPEP 714; 37 CFR 1.121. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Response to Arguments

8. Applicant's arguments filed on June 3, 2010, with respect to claim 1, have been fully considered but they are not persuasive:

In regards to claim 1, Applicant argues that Burroughs et al does not teach the claimed cylindrical insert and that the bulkhead ledges [178][180] cannot possibly comprise the insert of Applicant's invention as that term is defined in the instant application (Remarks, pages 1-2). Examiner disagrees. First, Burroughs et al does teach a cylindrical insert in the form of two bulkhead ledges [178][180]. These bulkhead ledges [178][180] are half cylindrical in shape and when placed or connected together, the two bulkhead ledges form a cylindrical shape. The resultant insert [178][180] is rotationally and axially fixed to the housing [22] (Figures 1-5) and threadedly engaged to the piston rod [38] via the tangs [182][184]. The resultant insert extends longitudinally in a proximal direction enclosing a portion of the piston rod (Figure 1). Applicant argues that the bulkhead ledges are not a single structure; however, the claim does not require the insert to be a single structure. Second, there is no special definition in Applicant's specification for the term "insert"; hence the broadest reasonable interpretation for the term "insert" has been used to interpret the meaning of the term in the claim. An "insert" is "something that is inserted

or is for insertion” (*Merriam-Webster OnLine.*). Since, the bulkhead ledges [178][180] are inserted within the housing [22], they can be interpreted as the claimed insert.

9. Applicant’s arguments, see pages 2-5, filed on June 3, 2010, with respect to claim 2 have been fully considered and are persuasive. The rejection of January 6, 2010, has been withdrawn.

Allowable Subject Matter

10. Claims 2-4, 7-9, 11-15, 17, and 18 are allowed.

In regards to independent claim 2, the prior art of record does not disclose or render obvious at the time the invention was made the combination as claimed, specifically including a piston rod that is rotatable in only one direction relative to a housing, an insert located in the housing threadedly engaged with the piston rod, a ratchet associated with the insert configured to allow the piston rod to rotate only in a single direction through the insert, and a drive sleeve which is axially displaceable but not rotatable with respect to the piston rod. Dependent claims 3, 4, 7-9, 11-15, 17, and 18 are allowed by virtue of being dependent upon independent claim 2. The allowability, of dependent claims 5, 6, 10, and 16, cannot be determined at this time since the text of claims 5, 6, 10, and 16 has been omitted.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Shefali D Patel/
Examiner, Art Unit 3767
08/04/2010

/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767